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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,627	07/16/2007	Tetsuji Yoshimura	063012	4866

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EXAMINER

SERGEANT, RABON A

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

03/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/594,627

Applicant(s)

YOSHIMURA ET AL.

Examiner

Rabon Sergeant

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/28/06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 26, 2009 has been entered.
2. Newly amended claims 8 and 9 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 8 and 9, as instantly amended, are now directed to a method for bonding body tissues using the medical adhesive of claim 1. There is considered to be lack of unity between the medical adhesive of claims 1-7 and 10-14 and the instantly claimed method of use of claims 8 and 9, because the medical adhesive lacks an inventive step, in view of the teachings set forth below with respect to WO 03/051952 in view of Hiraishi et al. ('266) or Nakamura et al. (US 2003/0225239) or Sparer et al. (US 2004/0033251) or Felt et al. (US 2005/0060022), and is therefore not a technical feature that defines a contribution over the prior art. See MPEP 1850.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 8 and 9 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 11 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 11, in view of the carbon atom range of 5 to 22 within claim 1, it cannot be determined how to interpret or reconcile the 1 to 20 carbon atom range of the dependent claim. Furthermore, the use of "may" renders the claim indefinite, because it is unclear if or to what extent the language denoted by "may" is optional.

With respect to claim 14, the language, "type", so extends the scope of the term that it is rendered indefinite. *Ex parte Copenhagen*, 109 USPQ 118.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-7 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 03/051952 in view of Hiraishi et al. (*266) or Nakamura et al. (US 2003/0225239) or Sparer et al. (US 2004/0033251) or Felt et al. (US 2005/0060022).

WO 03/051952 discloses medical adhesives having the same properties and derived from the same reactants as those instantly claimed; however, while WO 03/051952 discloses that

stabilizers may be incorporated within the adhesive composition, the reference fails to disclose applicants' instantly claimed phenolic radical scavenger. However, the position is taken that the use of phenolic antioxidants that correspond to applicants' claimed phenolic radical scavenger within polyurethanes, suitable for use within medical applications, was known at the time of invention. This position is supported by the teachings of the secondary references. See Example 1 within Hiraishi et al. See paragraphs [0168], [0175], and [0177]-[0180] within Nakamura et al. See paragraph [0121] within Sparer et al. See Table 1 within Felt et al. Since it has been held that it is *prima facie* obvious to use a known component for its art recognized function, the position is taken that it would have been obvious to incorporate known phenolic antioxidants within the urethane based composition of the primary reference, so as to obtain an improved and further stabilized adhesive composition. *In re Linder*, 173 USPQ 356. *In re Dial et al.*, 140 USPQ 244.

6. It is noted that GB 2399345 is the English language equivalent of WO 03/051952; therefore, applicants are directed to this document for a full description of the adhesive composition within WO 03/051952. Specifically, applicants are directed to pages 8, 9, 11, 28, 40, and 47 of the GB reference.
7. Applicants have argued that their showings of unexpected results rebut the *prima facie* case of obviousness. In response, the examiner has considered applicants' examples within the specification and the examples within applicants' 37 CFR 1.132 declaration, filed December 26, 2007; however, the showings are insufficient to rebut the *prima facie* case of obviousness, because, despite applicants' remarks, the examples continue not to be commensurate in scope with the claims. It has been held that the claims must be commensurate in scope with any

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showing of unexpected results. *In re Greenfield*, 197 USPQ 227. It has further been held that a limited showing of criticality is insufficient to support a broadly claimed range. *In re Lemin*, 161 USPQ 288. Applicants' examples are limited to specific polyisocyanates, specific polyol compounds having specific characteristics, and specific phenolic radical scavengers used in specific amounts; however, applicants' claims are not so limited. Furthermore, within pages 9-11 of the response of February 26, 2009, applicants provide argument why one would expect components not exemplified but encompassed by the claims to yield results comparable to the results set forth within the examples. Firstly, it is noted that the components encompassed by the claims are not commensurate in scope even with these additional arguments. Secondly, applicants' arguments amount to little more than unsubstantiated opinion; applicants have not presented any factual evidence that supports their position for the full scope of components encompassed by the claims. *In re Pike et al.*, 84 USPQ 235. *In re Renstrom*, 81 USPQ 390. Accordingly, since the scope of the claims is far broader than the scope of the examples and showings, applicants have failed to provide adequate showings of unexpected results for the full scope of the claims. Accordingly, the prior art rejection has been maintained for the reasons of record.

Any inquiry concerning this communication should be directed to R. Sergent at telephone number (571) 272-1079.

/Rabon Sergent/
Primary Examiner, Art Unit 1796

R. Sergent
March 23, 2009